Citation:

Mosley BS, Hobbs CA, Flowers BS, Smith V, Robbins JM. Folic acid and the decline in neural tube defects in Arkansas. *J Ark Med Soc*. 2007; 103 (10): 247-250.

PubMed ID: 17487022

Study Design:

Population-based longitudinal cohort study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

- To summarize efforts by the Arkansas Reproductive Health Monitoring System (ARHMS) and the Arkansas Folic Acid Coalition to increase the awareness and use of folic acid in Arkansas
- To show how the rates of NTDs in the state have declined over the past 10 years
- To estimate the direct health care and productivity cost savings to Arkansans over that time.

Inclusion Criteria:

Eligible for ARHMS registry

- The mother must be an Arkansas resident at the time of delivery
- The eligible birth defect must be diagnosed by a physician
- The birth defect must have been diagnosed by the time the child is two years old
- Eligible birth defects among live born or stillborn infants, miscarriages or electively terminated pregnancies.

Eligible for the Arkansas Folic Acid Coalition

- Women of reproductive age
- Postpartum women (n=300)
- Health care providers statewide
- Families affected by an NTD
- Women receiving routine obstetric care
- Hispanic women.

Exclusion Criteria:

Not described in the article. It is assumed by reviewer that people who did not meet inclusion criteria or non-Arkansas resident were excluded from the study.

Description of Study Protocol:

Recruitment

ARHMS, one of the oldest active birth defect surveillance systems in US, was founded in 1980, which monitored birth defects among Arkansas women.

Design

Population-based longitudinal cohort study.

Dietary Intake/Dietary Assessment Methodology

Not applicable.

Blinding Used

- Birth defect was diagnosed by a physician
- Abstractors, certified in health information management and specifically trained in birth defects surveillance, visited health care centers at regular intervals where birth defects may be diagnosed.

Intervention

Efforts by ARHMS and the Arkansas Folic Acid Coalition to increase the awareness and use of folic acid in Arkansas:

- Use of folic acid
- Fortification of cereal grains with folic acid
- Health education.

Statistical Analysis

Rates of neural tube defects (cases per 10,000 live births) were calculated.

Data Collection Summary:

Timing of Measurements

Between 1994 and 2003.

Dependent Variables

Rates of neural tube defects in Arkansas: Cases per 10,000 live births.

Independent Variables

Efforts by ARHMS and the Arkansas Folic Acid Coalition to increase the awareness and use of folic acid in Arkansas:

- Use of folic acid
- Fortification of cereal grains with folic acid
- Health education.

Control Variables

Not applicable.

Description of Actual Data Sample:

- *Initial N:* Not described
- Attrition (final N): Not described
- *Age:* Childbearing age
- *Ethnicity:* White, African-American, Hispanic
- *Other relevant demographics:* Not described
- *Anthropometrics:* Not described
- *Location:* The state of Arkansas.

Summary of Results:

- Among Arkansas residents, supplement use was 32%
- Rates of NTDs declined from 11.9 per 10,000 births in 1994 to 1995 to 7.2 per 10,000 live births in 2002-03
- Among Hispanic births the most recent rate (10 per 10,000 births per year) was about half the rate (19.8 per 10,000 births per year) before public health interventions
- Among Whites NTD rates per 10,000 births declined from 13.5 per year to 8.7
- Rates per 10,000 births for blacks had increased slightly (5.8 to 6.6) but not statistically significant
- Rates of NTDs per 10,000 live births had declined most significantly in the Southeast (14.5 to 6.5) and Southwest (11.2 to 6.9), and also in the Northeast (13.3 to 8.8) and Northwest (11.9 to 8.4)
- Rates in the Central area had declined only slightly (10.3 to 10.1)
- From 1998 to 2003, NTDs occurred in 55 of the 74 counties in Arkansas
- At least one NTD affected pregnancy occurred in all counties in the Central region and in all but three counties in the Northwest
- Three pregnancies affected by anencephaly and nine pregnancies affected by spina bifida had been prevented each year since public health interventions had been taken place
- With the prevention of NTDs, direct savings to residents of the state were over $2.5 million per year, Arkansas families had saved over $7.2 million per year.

Author Conclusion:

- The Arkansas Reproductive Health Monitoring System (ARHMS) and the Arkansas Folic Acid Coalition have encouraged use of folic acid and monitored the impact of increased consumption of folic acid among Arkansans
- NTDs in Arkansas have declined 40% since intervention programs were implemented
- The greatest decline has been observed among white and Hispanic women
- Efforts to encourage folic acid consumption should continue to target Arkansas women.

Reviewer Comments:

- *In Arkansas, the impact of the campaign to encourage folic acid supplement use has been modest*
- *Neural tube defects have decreased in Arkansas most significantly among births to white and Hispanic women*
- *A continuing goal of the Arkansas Center and ARHMS is to identify and educate women*
- *Hispanic women where were observed to have higher rates of NTDs and where language barriers may be limiting the presentation of the folic acid message*
- *Younger women between 18 and 25 years old.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes

1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	???
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	No
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	???
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	???
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	???
4.1.	Were follow-up methods described and the same for all groups?	N/A
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	???
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A

5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	No
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	N/A
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	N/A
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	N/A
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes

7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	No
8.1.	Were statistical analyses adequately described and the results reported appropriately?	No
8.2.	Were correct statistical tests used and assumptions of test not violated?	???
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	No
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
8.6.	Was clinical significance as well as statistical significance reported?	No
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	No
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	No
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes